APR 15 2003

K023547

510(k) Summary
for
DioLase 980 D Diode Laser System

1. SPONSOR

American Dental Technologies, Inc.
5555 Bear Lane
Corpus Christi, TX 78405

Contact Person: Roger Dartt, CEO
Telephone: 1-800-320-1050

Date Prepared: October 11, 2002

2. DEVICE NAME

Proprietary Name:	DioLase 980 D Laser System
Common/Usual Name:	Dental Laser System
Classification Name:	Laser Surgical Instrument

3. PREDICATE DEVICES

BioLitec Smilepro 980 nm Diode Laser

4. INTENDED USE

The Diolase 980 D Diode Dental Laser System is intended for use in the following procedures: Frenectomy, Frenotomy, Biopsy, Operculectomy, Implant Recovery, Gingivectomy, Gingivoplasty, Gingival Troughing, Crown Lengthening, Hemostasis of Donor Site, Removal of Granulation Tissue, Laser-assisted Flap Surgery, Debridement of Deseased Epithelial Lining, Incisions and Draining of Abscesses, Tissue Retraction for Impressions, Papillectomy, Vestibuloplasty, Excision of Lesions, Leukoplakia, Exposure of Unerupted/Partially Erupted Teeth, Removal of Hyperplastic Tissues, Treatment of Aphthous Ulcers, Sulcular Debridement, Pulpotomy, Pulpotomy as an Adjunct to Root Canal Therapy, and Light Activation of Bleaching Materials.

5. DEVICE DESCRIPTION

The Diolase 980 D Diode Dental Laser System is a portable instrument intended for ablating, incising, excising, and coagulating intraoral soft tissue (including the marginal and interdental gingival) using a contact fiber optic delivery system.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The Diolase 980 D Diode Dental Laser System has the same intended use and the same or substantially equivalent technical specifications and mechanism of action as compared with the named predicated devices. The comparison of specifications are as follows:

Specifications	**Biolitec Smilepro 980**	**ADT Diolase 980 D**
Wavelength	980 nm	980 nm
Output Power	15W	15W
Power Range	1-15W	.2-15W
Increments	1W	.2W – 1W
Operating Modes	Pulsed or Continuous	Pulsed or Continuous
Pulse Duration ON	.01 to 99.9 Sec.	.01 to 99.9 Sec.
Pulse Duration OFF	.01 to 99.9 Sec.	.01 to 99.9 Sec.
Aiming Beam	635 nm; 4mW; Red	635 nm; 4mW; Red
Cooling	Air Cooled	Air Cooled
Weight	15 lbs. (9 kg)	11 lbs. (5 kg)
Dimensions	14" x 9" x 7"	14" x 9" x 3"
Power Requirements	110/220 V	110/220 V

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2003

Ms. Marcia Van Valen
Regulatory Specialist
American Dental Technologies, Inc.
12 Prairie Falcon
Aliso Viejo, CA 92656

Re: K023547
Trade/Device Name: Diolase 980 D Diode Dental Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 15, 2003
Received: January 16, 2003

Dear Ms. Van Valen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Notification: K023547

Device Name: Diolase 980 D Diode Dental Laser System

Indications for Use:

The following indications for use are the same as those approved on the predicate device. The DioLase 980 D Diode Dental Laser System is intended for the following applications on intraoral and extraoral soft tissue (including marginal and interdental gingival and epithelial lining of free gingival): Frenectomy, Frenotomy, Biopsy, Operculectomy, Implant Recovery, Gingivectomy, Gingivoplasty, Gingival Troughing, Crown Lengthening, Hemostasis of Donor Site, Removal of Granulation Tissue, Laser-assisted Flap Surgery, Debridement of Diseased Epithelial Lining, Incisions and Draining of Abscesses, Tissue Retraction for Impressions, Papillectomy, Vestibuloplasty, Excision of Lesions, Leukoplakia, Exposure of Unerupted/Partially Erupted Teeth, Removal of Hyperplastic Tissues, Treatment of Aphthous Ulcers, Sulcular Debridement, Pulpotomy, Pulpotomy as an Adjunct to Root Canal Therapy, and Light Activation of Bleaching Materials.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K023547

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)